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ORIGINAL ARTICLE

# Immediate Echocardiographic Surveillance After Transcatheter Closure of a Patent Ductus Arteriosus: A Feasible Method to Assess Residual Shunt

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Received: Feb 9, 2009  
Revised: Jul 3, 2009  
Accepted: Jul 31, 2009

## KEY WORDS:

coil;  
echocardiography;  
hemolysis;  
patent ductus arteriosus;  
residual shunt

**Background:** To evaluate the feasibility of echocardiography after transcatheter closure of patent ductus arteriosus (PDA) with coils.

**Methods:** Between April 1998 and December 2006, 131 patients had transcatheter coil occlusion of their PDA using Gianturco coils. We hypothesized that post-procedural hemolysis would not occur if a residual shunt <1 mm or if no continuous waveform was detected by echocardiography. Immediately after coil implantation, patients without and with a residual shunt as detected by echocardiography were designated to groups A and B, respectively. The clinical presentations, laboratory data and outcomes were compared between the two groups.

**Results:** There were 101 patients in group A and 30 patients in group B. Patients in group B had larger ductal diameter ( $2.8 \pm 0.9$  mm vs.  $1.6 \pm 0.8$  mm;  $p < 0.001$ ), larger Qp/Qs ( $1.9 \pm 0.9$  vs.  $1.3 \pm 0.4$ ;  $p = 0.001$ ), higher frequency of more than one coil used (14/30 vs. 11/101;  $p < 0.001$ ), and female predominance (22/30 vs. 53/101;  $p = 0.043$ ) compared with group A. Trivial residual shunt was noted in 6 patients in group A and 20 patients in group B on the day after embolization. All shunts spontaneously closed within 6 months in patients of group A, while five patients in group B had a persistent shunt at the 1-year follow-up and thereafter. Although the patients in group B had higher residual shunt rate than group A during follow-up ( $p < 0.001$ ), none of these patients suffered from hemolysis.

**Conclusion:** Echocardiography is a feasible tool to assess residual shunt after PDA closure. If a residual shunt <1 mm or if no continuous waveform is detected by echocardiography, the risk of developing hemolysis is low.

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## 1. Introduction

Since the first transcatheter closure of patent ductus arteriosus (PDA) using Gianturco coils was reported by Cambier et al in 1992,<sup>1</sup> the procedure has gained increasing popularity worldwide. The technique is simple, involving a small delivery catheter, low cost, and has a high success rate. However, the method carries some risks for complications, and post-procedural hemolysis is one of the most serious of such complications.<sup>2,3</sup>

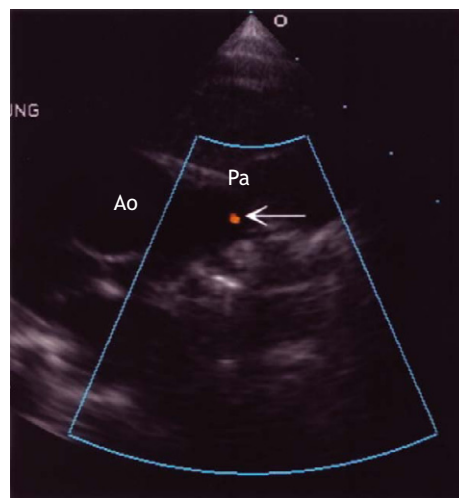
To our knowledge, there is currently no method that prevents hemolysis. The use of echocardiography for patients who receive transcatheter closure of PDA in the catheterization laboratory has proved to be a valuable method.<sup>4</sup> The objective of this study was to evaluate the feasibility of using echocardiography to assess residual shunt, and to design a strategy that prevents hemolysis after transcatheter closure of PDA with coils.

## 2. Materials and Methods

Between April 1998 and December 2006, 171 patients with PDA were referred to our institution for transcatheter closure. Of these, 131 patients were included in this study and successfully managed with Gianturco coils (Cook Cardiology, Bloomington, IN, USA). A total of 40 patients were excluded. Of these, 33 patients had PDA ( $>4$  mm) and/or associated with pulmonary hypertension; 26 of the 33 patients were referred to surgical ligation, and 7 of the 33 were managed with Amplatzer duct occluder. The remaining seven patients with ductal diameter  $<1$  mm, which precluded transcatheter closure were also excluded from study.

Informed consent was obtained from the patients' parents. The study was approved by the human investigation committee of our institutional review board. All procedures were performed under local anesthesia. Patients 6 years of age or less were sedated with intravenous ketamine or diazepam. All patients received prophylactic antibiotic treatment with one dose of cefazolin (25 mg/kg) given intravenously. Prior to the attempted occlusion, the minimal PDA diameter was measured by aortography. The diameter of the implanted coil was at least 1.7 times the minimum PDA diameter and the length of the coil was sufficient to produce four or five loops.

All patients underwent transthoracic echocardiography within 15 minutes after transcatheter deployment of the coils in the catheterization laboratory. Echocardiography was performed using the Philips SONOS 5500 or 7500 system (Philips, Andover, MA, USA) and 5 MHz to 8 MHz transducers.



**Figure 1** Immediately after coil implantation, a tiny jet (arrow) was visualized by color Doppler in the parasternal short-axis view. The residual shunt had spontaneously closed at 3-month follow-up.

The presence of a residual shunt was evaluated by echocardiography with color flow Doppler in the parasternal short-axis view. The width of the residual shunt was measured at the junction of the PDA and the pulmonary artery by color Doppler (Figure 1). The waveform of the residual shunt was determined by continuous-wave Doppler. Aortography was performed at the end of the procedure as a control for comparison with echocardiography.

We hypothesized that post-procedural hemolysis would not occur if a residual PDA shunt of  $<1$  mm or if no continuous waveform was detected by echocardiography. The number of coils used in the procedure was determined by the operator based on the ductal diameter and personal experience. Immediately after coil implantation, patients without and with a residual shunt as detected by echocardiography were designated to groups A and B, respectively. Group B was further subdivided as residual shunt  $<1$  mm or no continuous waveform, and residual shunt  $\geq 1$  mm or with continuous waveform. For all patients in group A, and for patients in group B who had a residual shunt  $<1$  mm or no continuous waveform, we did not use more coils in the catheterization laboratory. In patients in group B with a residual shunt  $\geq 1$  mm, or with a continuous waveform on echocardiography, additional coils were implanted until one of the following conditions was fulfilled: no residual shunt, residual shunt  $<1$  mm, or no continuous waveform shunt detected by echocardiography. Follow-up echocardiography was performed the next day, at 3, 6 and 12 months after the procedure, and annually thereafter. Inspection of patients' urine and skin color was done to detect the presence of hemolysis.

Results are expressed as means  $\pm$  standard deviation for continuous variables or as the number of

cases and percentages for categorical variables. Comparisons between groups were done with unpaired Student's *t* test for continuous variables, and  $\chi^2$  test and Fisher's exact test for categorical variables. Statistical analysis was performed using SPSS (SPSS Inc., Chicago, IL, USA). A *p* value <0.05 was considered statistically significant.

### 3. Results

A total of 131 patients underwent successful coil implantation in our study. The age of patients ranged from 4 months to 18 years (mean,  $3.0 \pm 3.7$  years). The body weight ranged from 5.4 kg to 63.0 kg (mean,  $13.9 \pm 9.0$  kg). Based on Doppler echocardiographic findings, 101 patients were allocated to group A and 30 patients to group B. The immediate residual shunt was 22.9% (30/131). The clinical data and outcomes of groups A and B are summarized in Table 1. In group A, 90 patients had one coil and 11 patients had two coils implanted. In group B, 16 patients had one coil, and 14 patients required two or three coils to achieve the criteria of a residual shunt <1 mm or no continuous waveform detected before leaving the catheterization laboratory.

Patients in group B had bigger PDA diameter ( $2.8 \pm 0.9$  mm vs.  $1.6 \pm 0.8$  mm;  $p < 0.001$ ), larger Qp/Qs ( $1.9 \pm 0.9$  vs.  $1.3 \pm 0.4$ ;  $p = 0.001$ ) and higher frequency of more than one coil used (14/30 vs. 11/101;  $p < 0.001$ ) than patients in group A. There were more female than male patients in group B compared with those of group A (22/30 vs. 53/101;  $p = 0.043$ ). There were no statistically significant differences between both groups in terms of age ( $p = 0.764$ ), body weight ( $p = 0.775$ ) and duration of follow-up ( $p = 0.325$ ). The sensitivity for detecting residual shunt was 77.1% and 72.5% for echocardiography and aortography, respectively. The results of the residual PDA shunt are summarized in Table 2. PDA recanalization was noted in six patients in group A on the first post-procedural day. All of these residual shunts spontaneously closed within 6 months of

follow-up. Twenty patients in group B had a residual shunt on the first post-procedural day. Spontaneous closure of the residual shunts occurred in 15 patients within 6 months, while five patients had a trivial shunt at 1 year follow-up, which remained thereafter. Although the residual shunt rate was higher in group B than in group A during the follow-up period (Table 2,  $p < 0.001$ ), none of these patients suffered from hemolysis.

### 4. Discussion

The potential causes of morbidity after transcatheter closure of PDA include device embolization, obstruction of the pulmonary arteries or the thoracic aorta, persisting residual shunt and hemolysis. Device embolization, obstruction of the great vessels or malposition can be recognized and easily managed by an experienced cardiologist in the catheterization laboratory. However, post-procedural intravascular hemolysis due to insufficient PDA closure remains problematic and unpredictable.

Angiography is regarded as the gold standard to assess residual shunts after transcatheter PDA closure. Angiography allows for evaluation of the device position, residual leak and the need for implantation of additional coils. Zellers et al<sup>5</sup> recommended that patients should leave the catheterization laboratory without any residual shunt to prevent hemolysis. However, immediate residual shunt is very

**Table 2** Patients with residual shunt detected by Doppler echocardiography

Time after procedure	Group A (n=101)	Group B (n=30)	<i>p</i>
1 d	6/101	20/30	<0.001
3 mo	1/101	12/30	<0.001
6 mo	0/101	5/30	<0.001
12 mo	0/101	5/30	<0.001

**Table 1** Clinical manifestations of patent ductus arteriosus after transcatheter coil embolization

	Patients with no residual shunt (n=101)	Patients with residual shunt (n=30)	<i>p</i>
Age (yr)	$3.1 \pm 3.7$	$2.8 \pm 3.9$	0.764
Sex (males/females)	48/53	8/22	0.043*
Body weight (kg)	$14.0 \pm 8.9$	$13.5 \pm 9.2$	0.775
Arterial duct diameter	$1.6 \pm 0.8$	$2.8 \pm 0.9$	<0.001*
Qp/Qs	$1.3 \pm 0.4$	$1.9 \pm 0.9$	0.001*
More than one coil used	11/101	14/30	<0.01*
Follow-up (yr)	$4.6 \pm 2.3$	$5.1 \pm 2.2$	0.325

\* $p < 0.05$ . Qp=pulmonary blood flow; Qs=systemic blood flow.

common, with an incidence ranging from 32% to 42% in published series.<sup>5-7</sup> Although the majority of patients with residual shunts are classified as silent PDA and spontaneous closure of these PDA might occur within 3–6 months, Shim et al<sup>7</sup> reported that 7% of patients with residual PDA will require a second procedure to close the shunt. Therefore, predicting the clinical outcome of residual shunt based on angiography remains defective.

Hemolysis after PDA closure by coils is due to a residual shunt with high velocity flow through the implanted device, leading to mechanical destruction of the erythrocytes. The reported incidence of hemolysis ranged from 1.0% to 3.6%.<sup>2,8,9</sup> For PDA with a diameter >3mm, the incidence is up to 18.8%.<sup>10</sup> The reported risk factors for insufficient coil occlusion included large ductus, young age and a small ratio of the loop diameter to the ductal diameter.<sup>2,8</sup> Hemolysis was typically noted within 24 hours after the procedure but could also occur weeks to months after the intervention. Once hemolysis has occurred, severe anemia or renal failure may follow.<sup>2</sup> Remedial procedures include conservative treatment with blood transfusion, immediate deployment of an additional coil to close the residual leak, removal of the coils, or surgery.<sup>11,12</sup> In our study, although patients in group B had larger PDA diameter than patients in group A, none of the patients with a residual shunt <1 mm or no continuous waveform detected developed hemolysis. Although our strategy could not assure complete closure of the PDA all the time, the strategy effectively prevented hemolysis.

In the Magee et al<sup>13</sup> report of patients with Doppler color flow mapping for residual shunt, seven of the nine patients with a continuous high velocity residual shunt required treatment with a second device after a mean duration of 2 years, and the remaining two patients exhibited continuous flow during follow-up. By contrast, patients without a continuous flow jet are more likely to exhibit spontaneous closure.<sup>13</sup> These results are in line with those of our study.

Echocardiography was recently reported as a useful tool for evaluating patients after transcatheter closure of PDA.<sup>4,7,13</sup> In our study, according to the echocardiographic criteria for managing PDA patients in the catheterization laboratory, no patient suffered from hemolysis after transcatheter closure of PDA. In addition, there were two additional benefits observed in our study. First, for patients in group A, post-procedural angiography could be replaced by echocardiography because the results of the two studies were very similar. This would be beneficial in reducing radiation exposure and contrast dosage in these patients. Second, patients in group B with a residual shunt of <1 mm or with no

continuous waveform detected, no additional coils were required. This can decrease the number of coils implanted. Using fewer coils are advantageous, not only in shortening procedure and fluoroscopy time but also in reducing the risk of left pulmonary artery stenosis.<sup>14</sup> In our study, most PDAs (81%, 106/131) could be closed by one coil; none of the patients developed pulmonary artery stenosis.

The principal limitation of our study was that it was retrospective and nonrandomized. Most patients (104/131) had a ductus diameter of 3 mm or less. These patients had a lower risk of developing hemolysis compared with those with a large PDA (>3 mm). Therefore, examining patients with a larger PDA will be valuable in evaluating and verifying the proposed echocardiography-guided management strategy. However, with immediate echocardiography after transcatheter closure of PDA, the criteria of a residual shunt <1 mm or no continuous waveform detected by echocardiography proved to be a good approach for preventing post-procedural hemolysis.

In conclusion, echocardiography is a feasible tool to assess residual shunt after PDA closure. If a residual shunt <1 mm or no continuous waveform is detected by echocardiography, the risk of developing hemolysis is low.

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